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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

STATE OF CALIFORNIA *ex rel*. JAYDEEN VICENTE and JAYDEEN VICENTE Individually, Relators, v. ELI LILLY AND COMPANY, Defendant.	Case No. 07-cv-04911-SI Assigned to: Hon. Susan Illston **NOTICE OF MOTION AND MOTION TO DISMISS UNDER RULES 12(b)(1), 12(b)(6) AND 9(b); MEMORANDUM OF POINTS & AUTHORITIES IN SUPPORT THEREOF** [Proposed] Order Granting Motion to Dismiss With Prejudice Filed Concurrently Herewith Date: November 16, 2007 Time: 9:00 a.m. Place: Courtroom 10, 19th Floor

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STATUTES

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on November 16, 2007 at 9 a.m. or as soon thereafter as this matter may be heard by the above-entitled Court, located at 450 Golden Gate Avenue, San Francisco, California, in the courtroom of the Honorable Susan Illston, Defendant will and hereby does move this Court, pursuant to Fed. R. Civ. P. 9(b), 12(b)(1) and 12(b)(6) to dismiss the complaint of *qui tam* Plaintiff/Relator Jaydeen Vicente. The grounds for this motion are that no court has subject matter jurisdiction over plaintiff's False Claims Act allegations; that plaintiff has failed to meet the pleading requirements of Fed. R. Civ. P. 9(b); and that the complaint fails to state a claim upon which relief can be granted, specifically: plaintiff lacks standing to bring its Unfair Competition Law and False Advertising Law claims and has not pled the required elements to allege violation of these statutes or of the California False Claims Act.

This motion is based on this notice of motion, the accompanying memorandum and points of authorities, the concurrently-filed request for judicial notice, the exhibits attached thereto and declaration in support thereof, the pleadings and other papers on file in this action, and on such other evidence and argument as may be presented to the court on reply and at the time of hearing.

INTRODUCTION

Eli Lilly and Company ("Lilly" or "the Company") developed, manufactures and sells Zyprexa®, one of a class of medications called atypical antipsychotics. Zyprexa is approved by the FDA for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and maintenance treatment in bipolar disorder. Zyprexa also can be prescribed – lawfully – by physicians for various other psychiatric disorders as they see fit.

As widely reported in the press in recent years, Zyprexa, like many pharmaceutical products today, has come under attack on a variety of fronts. A number of personal injury suits have been filed against the Company, which by and large have been consolidated in a federal MDL proceeding pending before Judge Weinstein the Eastern District of New York since 2004. Lilly has resolved a substantial number of those cases. In 2004, Lilly learned that the United States Attorney's Office for the Eastern District of Pennsylvania had commenced a civil investigation relating to Lilly's U.S. marketing and promotional practices with respect to Zyprexa and other

drugs,[1] and numerous other states, including California, have either initiated investigations of the company's marketing and promotional practices relating to Zyprexa or filed suit claiming some form of damages allegedly stemming from those practices.[2] Several private insurers have also sued Lilly, citing its sales and marketing practices. Both the existence of these cases and the allegations contained therein have been the subject of a great deal of press coverage, including in a series of front page articles in the *New York Times*.

Seeking to capitalize on the notoriety regarding Lilly's alleged off-label marketing of Zyprexa and to capture the potential bounty made available to whistleblowers, Relator Vicente filed this *qui tam* action under the California False Claims Act ("CFCA"). Relator's complaint, however, simply mirrors the many allegations against Lilly previously made public in media reports.

California law makes plain that a private party may not pursue a CFCA lawsuit as a *qui tam* plaintiff, and the courts lack jurisdiction over such claims, where the allegations are substantially similar to prior public disclosures that would have alerted the State to its potential claims. That is precisely the case here. And Relator cannot avoid dismissal on jurisdictional grounds by claiming to be the "original source" for these media reports because she fails to meet each of the statutory requirements for claiming that status. In short, Relator here serves no legitimate function because prior public disclosures put California on notice of the substance of her claims well before her suit was filed.

Nor may Relator proceed under California Business & Professions Code §§17200 or 17500. Those statutes were recently amended to make plain that only certain enumerated prosecutors may bring an action on behalf of the state and that private parties, like the Relator here, lack standing to assert a claim unless they personally suffered injury as a consequence of the challenged conduct. Relator alleges no such injury and thus lacks standing.

[1] As Lilly disclosed in its 2004 Form 10-K, in response to requests for documents in this investigation, it produced, among other things, "documents relating to communications with physicians and the remuneration of physician consultants and advisors." *See, e.g.*, RJN Ex. 1. Lilly Form 10-K for the fiscal year ending December 2004, p. 15.

[2] As disclosed in the Company's 2007 Form 10-K, the State of California Attorney General issued a subpoena to Lilly requesting documents relating to, among other things, marketing and promotional practices with respect to Zyprexa and remuneration of healthcare providers. *See, e.g.*, RJN Ex. 4. Lilly Form 10-K for the fiscal year ending December 2006, p. 36.

Even if Relator had standing and were jurisdictionally able to proceed, her complaint fails to state a claim under Rules 9(b) and 12(b)(6) because it never identifies with particularity any false claims that were ever submitted to the State of California, much less who submitted any such claims or when they were submitted. Moreover, putting aside these flaws, Relator cannot state a claim because, notwithstanding Relator's breathless rhetoric to the contrary, seeking reimbursement for off-label usage of a drug is not illegal and does not constitute a materially false statement in the context of California's medical reimbursement claims process.

FACTUAL BACKGROUND

This is a *qui tam* action on behalf of the State of California under the California False Claims Act, Cal. Gov't Code § 12650 *et seq*., filed by Relator Jaydeen Vicente against her former employer, Eli Lilly and Company. The complaint was filed on May 11, 2007. Compl. ¶ 17. California has declined to participate in the action. *See* Notice of Election to Decline Intervention Pursuant to Government Code Section 12652(c)(8)(D)(ii), filed July 10, 2007 (attached to Notice of Removal).

The complaint does not allege that Lilly directly submitted any false claims to the State. Nor does it identify any other person who allegedly submitted false claims for Zyprexa. Indeed, it does not specify any false claims at all.[3] Instead, the Complaint consists of a lengthy recitation of alleged regulatory violations by Lilly that the Relator argues must have "caused" unspecified physicians to submit "false" claims. In particular, Relator alleges that Lilly somehow caused the submission of false claims by: (1) promoting Zyprexa to treat conditions for which the FDA had not approved Zyprexa, Compl. ¶ 2, and (2) paying alleged "kickbacks" to prescribing physicians in the form of speaking fees, honoraria, and the like. *Id*. ¶ 6. On this basis, Relator alleges that Lilly violated, and conspired to violate, the California False Claims Act (Counts I and II), and violated the California Business and Professions Code ¶¶ 17200 (Count III) and 17500 (Count IV).

[3] Nor does the Complaint, as discussed in more detail below, even allege that Relator was the source for most of the information contained in the allegations. Of the 225 paragraphs in the Complaint that precede the causes of action, Relator claims personal knowledge only with respect to 22 paragraphs, (¶¶ 71-93), the bulk of which simply detail the history of her employment with Lilly. Compl. ¶ 17.

The essence of Relator's allegations regarding Zyprexa promotion is that Lilly "unlawfully" promoted the drug "for non-indicated uses and non-medically necessary uses including . . . behavioral disorders, attention deficit disorder . . . Alzheimer's, dementia and aggression and agitation associated with dementia and Alzheimer's." *Id.* ¶ 49. As purported support for this allegation, Relator describes some of Lilly's Zyprexa promotional materials, focusing in particular on certain hypothetical patient profiles contained therein. *See, i.e., id.* ¶¶ 127, 129. Relator also alleges that Lilly marketed Zyprexa to primary-care physicians through a campaign focusing on symptoms of mental illness (rather than diagnosis), *id.* ¶¶ 167-173, and once again including hypothetical patient profiles. *See, i.e., id.* ¶¶ 172-173.

Relator's "kickback" claim centers on allegations that Lilly trained and paid physicians to speak at seminars and provided entertainment, food, and wine to physicians participating in these seminars. *Id.* ¶¶ 152-166; 192-201. Relator also alleges that Lilly's efforts to promote Zyprexa included accessing confidential patient records protected by HIPAA in order to identify physicians who might prescribe Zyprexa. *Id.* ¶¶ 134-143.

As set forth in detail below, nearly identical allegations regarding Lilly's promotion of Zyprexa were widely reported by prominent publications such as the *New York Times, Los Angeles Times, Wall Street Journal, Associated Press, Reuters, Dow Jones Business News* and the *Daily Mail*. In addition, both the Federal Government (through the United States Attorney in the Eastern District of Pennsylvania) and numerous state governments (including California) are investigating issues related to Zyprexa, including its marketing and promotion.[4]

On September 21, 2007, Lilly removed this case from California state court to the U.S. District Court, Northern District of California. Lilly now brings this motion to dismiss.

[4] Lilly publicly disclosed these investigations and lawsuits in its Form 10-K and 10-Q filings. *See, e.g.*, RJN Ex. 1-4, 26. Lilly Form 10-K for the fiscal year ending December 2004, pp. 13, 15 (disclosing MDL proceedings and investigation of United States Attorney for the Eastern District of Pennsylvania); Lilly Form 10-K for the fiscal year ending December 2005, pp. 21; 38-39 (disclosing same and adding disclosure of Florida Attorney General investigation); Lilly Form 10-K for the fiscal year ending December 2006, p. 36 (disclosing same and adding disclosure of California Attorney General investigation and multistate investigative effort being coordinated by an executive committee of attorneys general).

ARGUMENT

I. NO COURT HAS JURISDICTION OVER RELATOR'S CALIFORNIA FALSE CLAIM ACT CLAIMS

A. California Bars Suits Based Upon Previously Disclosed Allegations Where Relator is Not an Original Source

Relator's first two causes of action assert claims under California's False Claims Act, Cal. Gov't Code §§ 12650-12656. The CFCA is modeled after the Federal False Claims Act ("FCA") and federal decisions are therefore persuasive on the meaning of the CFCA. *State v. Altius Finance, S.A.*, 36 Cal. 4th 1284, 1299 (2005); *State of Cal. ex rel. Bowen v. Bank of America Corp.*, 126 Cal. App. 4th 225, 236, 240 n.11 (2005).

As with the FCA, the purpose of the CFCA is to protect the public fisc. *Wells v. One2one Learning Foundation*, 39 Cal. 4th 1164, 1196 (2006). The CFCA therefore creates incentives to private parties to ferret out fraud by making available a portion of any recovery to the *qui tam* plaintiff who pursues the action. *See American Contract Services v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854, 858 (2001); Cal Gov't Code § 12652(g). Thus, individuals with evidence of fraud are provided an incentive to come forward and disclose that evidence to the government. *Rothschild v. Tyco Int'l (US), Inc.*, 83 Cal. App. 4th 488, 495 (2000). Indeed, it is one of the prerequisites of maintaining a *qui tam* suit that the complaint be filed under seal and that the plaintiff share its evidence with the State Attorney General so that the State may decide whether to pursue the action. Cal. Gov't Code § 12652(c).

The risk to this statutory bounty program is "the danger of parasitic exploitation of the public coffers" by "opportunistic plaintiffs who have no significant information to contribute of their own." *State of California ex. rel. Grayson v. Pacific Bell Telephone* 142 Cal. App. 4th 741, 746 (2006), *quoting U.S. ex. rel. Springfield Terminal R_x v. Quinn*, 147 3rd 645, 649 (D.C. Cir. 1994). In other words, "providing cash bounties to freeloaders does not serve the purpose of the FCA to protect the public fisc." *Id., citing American Contract Services*, 94 Cal. App. 4th at 858.

In order to address the "freeloader" issue, the CFCA deprives courts of jurisdiction over claims based upon matters that have already been publicly disclosed by the news media. The

CFCA therefore provides, among other things, that:

> No court shall have jurisdiction over an action under this article based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in an investigation, report, hearing or audit conducted by or at the request of the Senate, Assembly, auditor or governing body of a political subdivision, or by the news media.

Cal. Gov't Code § 12652(d)(3)(A). This provision reflects the legislative effort to preclude parasitic or opportunistic actions. *City of Hawthorne ex rel. Wohlner v. H&C Disposal Co.*, 109 Cal. App. 4th 1668, 1678 (2003). "When there has been a public disclosure the governmental authority is already in a position to vindicate society's interests, and a *qui tam* action would serve no purpose." *Grayson*, 142 Cal. App. 4th at 748 (internal quotation and citation omitted). As the legislative history of the act makes clear, this provision "is intended to reward the first whistleblower, and to prevent other 'bandwagon' whistleblowers from reaping the benefits of the disclosure." Request for Judicial Notice in Support of Motion to Dismiss ("RJN") Exhibit 25, Certified Legislative History of Cal. Gov't Code § 12650-12656 at 230 (Report of the Senate Committee on Judiciary on AB 1441).

In assessing whether a complaint is "based upon" public disclosure of the allegations or transactions in the news media, it is irrelevant whether the Relator actually knew of or employed the public disclosures to prepare its complaint; rather "based upon" means supported by or "substantially similar to," so that the relator's independent knowledge of the information is irrelevant." *Grayson*, 142 Cal. App. 4th at 751-52; *see also U.S. ex rel. Biddle v. Board of Trustees of Leland Stanford Jr., Univ.*, 161 F. 3d 533, 539-40 (9th Cir. 1998), *cert. denied* 526 U.S. 1066 (1999).

The jurisdictional bar is "triggered whenever a plaintiff files a *qui tam* complaint containing allegations or describing transactions 'substantially similar' to those already in the public domain so that the publicly available information is already sufficient to place the government on notice of the alleged fraud." *Grayson*, 142 Cal. App. 4th at 748. The relevant inquiry is whether the allegations or transactions of the present complaint are "'substantially similar to those disclosed in the earlier … action,'" *U.S. ex rel Foundation Aiding The Elderly v. Horizon West*, 265 F. 3d 1011, 1015 (9th Cir. 2001), *quoting U.S. v. Hughes Aircraft Co.*, 102 F.3d 1027, 1033 (9th Cir. 1998), or

whether the "prior public disclosures contain[] enough information to enable the government to pursue an investigation against [defendant]," *U.S. v. Alcan Electrical and Engineering, Inc.*, 197 F. 3d 1014, 1019 (9th Cir. 1999). Thus, a claim is jurisdictionally barred where the "allegation repeats what the public already knows." *Wang v. FMC Corp.*, 975 F.2d 1412, 1417 (9th Cir. 1992).

There is one limited exception to this jurisdictional bar. If the action is based upon public disclosure by the news media, the relator may nevertheless proceed if she is an "original source." *Id*. California statutorily defines "original source" as a person with "direct and independent knowledge of the information on which the allegations are based, who voluntarily provided the information to the state . . . before filing an action based on the information, and whose information provided the basis or catalyst for the investigation, hearing, audit, or report that led to the public disclosure as described in subparagraph (A)." Cal. Gov't Code § 12652(d)(3)(B). This standard is in accord with the Ninth Circuit requirement under the FCA that the relator have direct and independent knowledge of the allegations, voluntarily provided the information to the government before filing the action, and had a hand in the public disclosure. *U.S. ex. rel. Zaretsky v. Johnson Controls, Inc.*, 457 F.3d 1009, 1013, 1021 (9th Cir. 2006).

Here, Relator's complaint is indisputably based upon public disclosure in the news media of the entire thrust of Relators complaint. Relator, moreover, fails to qualify under the "original source" exception to the CFCA's jurisdictional bar.

B. <u>This Action is Based Upon Previously Disclosed Allegations in the News Media</u>

1. <u>The Media Disclosed Lilly's Alleged Kickbacks and Off-Label Marketing to PCPs and Long Term Care Facilities for Treatment of the Elderly and Dementia</u>

Relator's allegations in this matter have been the subject of multiple public disclosures in the news media.[5]

[5] Because the prior disclosure bar is a jurisdictional one, the Court is free to consider matters outside the pleadings to determine its jurisdiction to hear Relator's claims. *Savage v. Glendale Union High School, Dist. No. 205, Maricopa County*, 343 F. 3d 1036, 1040 fn. 2 (9th Cir. 2003); *White v. Lee*, 227 F.3d 1214, 1242 (9th Cir. 2000). Moreover, even on a Rule 12(b)(6) motion, the court may consider matters subject to judicial notice under F.R.E. 201(b), such as press reports, particularly where, as here, they are not offered for the truth of the matter asserted but rather merely to establish that a disclosure was made. *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001). The court may do so without converting the motion to one for summary judgment. *Lee*, 250 F.3d at 688-89; *Louis v. McCormick & Schmick Restaurant Corp.*, 460 F. Supp. 2d 1153, 1155 (C.D. Cal. 2006).

As early as March 25, 2004, *The Wall Street Journal* and others reported the commencement of a federal investigation by the U.S. Attorney in the Eastern District of Pennsylvania into Lilly's marketing of Zyprexa. RJN Exhibits 7, 8, 9. Others in the news media speculated as to the nature of the investigation, citing "new federal guidelines [that] bar certain marketing practices that had been widely used, such as wining and dining doctors or flying them to paid vacations at resorts as a way of getting them to prescribe the company's products." RJN Ex. 10. (*Indianapolis Star*, March 26, 2004).

In December 2006, Lilly's marketing of Zyprexa was the subject of front page coverage in *The New York Times* that reads like a roadmap of Relator's complaint in this action.[6] Based on documents illegally leaked to it from ongoing litigation, *The New York Times* reported that "Eli Lilly encouraged primary care physicians to use Zyprexa, a powerful drug for schizophrenia and bi-polar disorder, in patients who did not have either conditions, according to internal Lilly marketing materials." RJN Ex. 12. (*The New York Times*, Dec. 18, 2006). The story continued that "Lilly told its sales representatives to suggest that doctors prescribe Zyprexa to older patients with symptoms of dementia." *Id.* The article claimed that Lilly advocated "dementia should be the first message of a campaign to primary doctors, according to the document, which appears to be part of a larger marketing presentation." *Id.* The article went on to report on "federal and state investigations over [Lilly's] marketing of Zyprexa" and a subpoena from the Florida Attorney General "seeking production of documents relating to sales of Zyprexa and [Lilly's] marketing and promotional practices with respect to Zyprexa." *Id.* The article even described the hypothetical patient profiles featured in Relator's complaint: "Eli Lilly created the profiles of patients whom it said would be suitable candidates for Zyprexa . . . The third patient was Martha…[who] was described as being agitated and having disturbed sleep, but without the symptoms of paranoia or mania that typically marked a person with schizophrenia or bi-polar disorder." *Id.* Another was "a profile of 'Donna,' a single mother in her mid-30's whose 'chief complaint is "I feel so anxious and irritable lately."'" *The*

[6] There had been prior disclosures of the allegations made in various contexts prior to *The New York Times* article. For example, Lilly disclosed the investigations and state action of which it became aware in its SEC filings. *See*, *supra*, footnotes 1, 2 and 4. In addition, plaintiffs had publicized their Zyprexa lawsuits in the press. *See* RJN Ex. 22. (Press Release, *Hersh & Hersh Targets Eli Lilly's Most Profitable Anti-Pyschotic Drug*, BUSINESS NEWSWIRE, Feb. 27, 2003).

New York Times reported that a physician complained that Lilly suggested Zyprexa for "an elderly female patient who was presented to her physician by her family complaining of insomnia, agitation, slight confusion and had no physical finding to explain her state." *Id.*

Other publications picked up on and repeated such statements which parallel Relator's allegations. The *Dow Jones Business News*, for example, picked up the story and focused on the contention that "Lilly promoted Zyprexa to primary care physicians for such unapproved conditions as dementia in the elderly." RJN Ex. 13. (*Dow Jones Business News*, Dec. 18, 2006). Days later, *The Los Angeles Times* ran an article by a primary care physician complaining of Lilly's marketing of Zyprexa. RJN Ex. 14. (*Los Angeles Times*, Dec. 25, 2006).

On January 5, 2007, the *Wall Street Journal* reported that state probes of Lilly were intensifying and that Connecticut "has expanded an investigation into Zyprexa's marketing practices and in an interview referred to a 'potentially huge claim' alleging that the company promoted the drug to Medicaid and non-Medicaid patients for unapproved uses." RJN Ex. 15. (*Wall Street Journal*, Jan. 5, 2007). Fatal to Relator's claims here, the article then revealed that "California's attorney general mounted an investigation in September into the company's marketing of Zyprexa." *Id.* Fifteen days later, *The New York Times* reported that Illinois and Vermont had demanded that Lilly turn over information about its promotion of Zyprexa and had joined a five state civil investigation into Lilly's promotional practices. RJN Ex. 13. (*New York Times*, Jan. 20, 2007). It continued, "Attorneys general in California and Florida may seek to recover Medicaid payments that the states made for Zyprexa." *Id.*

The news media also focused on the prescribing of Zyprexa in long term care facilities. On January 30, 2007, *The Daily Mail* ran an extensive investigative report under the sensationalist headline "Doped to Keep Them Quiet. Thousands of elderly patients are being subdued with 'chemical coshes' that – as this Special Investigation reveals – are putting their lives at risk." RJN Ex. 17 (*Daily Mail*, Jan. 30, 2007). This article was followed by news media reports of Senate testimony FDA scientist David Graham. RJN Ex. 18. (*USA Today*, Feb. 14, 2007). Asked if he had concerns about drugs, Graham reported that "off-label use of atypical anti-psychotic medications to sedate nursing home residents kills roughly 15,000 people a year." *Id.* This report

was followed by media accounts of "a congressional committee . . . looking into the 'off-label' use of drugs . . . The committees chairman, California Democrat Henry Waxman, . . . asked for marketing materials from three drug companies that have come under scrutiny over whether they promoted their products for unapproved uses." RJN Ex. 19. (*Wall Street Journal*, Mar. 6, 2007). "Senator Waxman's letter to Eli Lilly requested information about schizophrenia drug Zyprexa." RJN Ex. 20. (*New York Times*, Mar. 6, 2007).

Even the trade press highlighted allegations similar to Relator's here. The April 4, 2007 edition of *Rx Compliance Report* reported on Pennsylvania's lawsuit against Lilly to recoup money paid by the state for Zyprexa that allegedly resulted from certain promotional practices that encouraged overuse. RJN Ex. 23. (*Rx Compliance Report*, April 4, 2007). This report, just as the complaint here alleges, included "the strategic design of clinical trials, the support of continuing medical education programs, and the retention of physicians to assist the company in its promotional goals." *Id.* The same publication also highlighted Relators allegations here that Lilly promoted the use of Zyprexa to treat dementia symptoms in Long Term Care facilities. *Id. Rx Compliance Report* stated that a lawsuit filed by the State of Montana "charges Lilly created a 280 person sales force to promote Zyprexa exclusively for off-label uses, specifically for long-term care facilities . . .. The purpose and function of the LTC sales force was to market Zyprexa for 'a litany of non-indicated uses to control elderly patients who presented with agitation, anxiety, insomnia, or otherwise presented with symptoms that required time intensive care through sedation.'" *Id.*

2. <u>The Disclosures in the Media Are Substantially Similar to the Complaint and Provided Sufficient Information for the Government to Pursue a Claim</u>

The media disclosures described above parallel virtually every allegation set forth in the Relator's complaint in this matter: alleged kickbacks; alleged access to private patient records; alleged off-label marketing to both primary care physicians and long-term care facilities for the treatment of, among other things, dementia; and the use of patient profiles (including, specifically, those referenced in Relator's Complaint). Indeed, virtually every aspect of Relator's complaint is reflected in prior news media accounts. Many of the media disclosures, in fact, specifically reflected the allegations brought by other states seeking to recover payments made to Lilly by the state

Medicaid plans, including the disclosure that California, the party on whose behalf Relator purports to bring its suit, had already commenced its own investigation related to Zyprexa. Relator's complaint adds nothing to this mix.

That these disclosures bar Relator's complaint is made plain by *State ex rel. Grayson v. Pacific Bell Telephone Co*. 142 Cal. App. 4th 741. There, a relator alleged that phone companies were liable to escheat to the state the unclaimed or unused portion of pre-paid phone cards. There were, in the trade press, two articles that suggested that the unused portion of phone card constitute unclaimed property that should escheat to the state. *Id*. at 750-51. This was enough to bar plaintiffs claims because "the *qui tam* complaint substantially repeats what the public already knows." *Id*. at 752. It made no difference that the public disclosures did not identify the specific statutory violation or the particular type of fraud as long as the essential facts were disclosed. *Id*. ("'If a relator merely uses his or her unique expertise or training to conclude that the material elements already in the public domain constitute a false claim, then a qui tam action cannot proceed'") *quoting U.S. ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 688 (D.C. Cir. 1997). *See also U.S. ex rel. Hansen v. Cargill, Inc.*, 107 F. Supp. 2d 1172 (N.D. Cal. 2000).

Nor may Relator salvage her complaint by the addition of minor factual details. *Wang*, 975 F.2d at 1417 ("it is also true Wang's allegations about the Bradley is supported by a few factual assertions never before publicly disclosed; but, 'fairly characterized' the allegation repeats what the public already knows: that serious problems existed with the Bradley's transmission"); *U.S. ex rel. Rosales v. San Francisco Housing Authority*, 173 F. Supp. 2d 987, 996 (N.D. Cal. 2001) ("although the purported means by which SFHA's fraud was perpetrated may not have been commonly known, the prior public disclosures contained enough information to enable the government to pursue an investigation into them. This is enough to trigger the jurisdictional bar"). Here, all of the essentials regarding Lilly's alleged kickbacks and off-label marketing of Zyprexa were widely reported; that is enough to trigger the jurisdictional bar.

C. Relator Is Not An Original Source

In tacit recognition that the basis of the allegations have been widely reported in the news media, Relator alleges without any factual support that she is an "original source" under Cal.

Gov't Code § 12652(d)(3)(B). Compl. ¶¶ 20-23. In order to qualify as an original source, however, Relator must have personal knowledge of the relevant facts, must have shared those facts with the State before commencing litigation, and must been the catalyst for the prior public disclosure of those facts. Cal. Gov't Code §12652(d)(3)(B).

First, Relator has extraordinarily limited direct and personal knowledge of the allegations on which the complaint is based. Of the 225 paragraphs[7] of the Complaint that precede the causes of action, Relator claims personal knowledge with respect to only 22 paragraphs. Compl. ¶¶ 71-93. The rest are either "summary," "background" or, more tellingly, 115 paragraphs of "Additional Factual Basis of Lilly's Illegal Off-Label Marketing . . ." that commence at paragraph 99 with "Upon information and belief . . ." Compl. ¶¶ 99 *et seq.* Those few paragraphs as to which Relator claims personal knowledge, moreover, contribute nothing other than rehashed details. Nothing in these paragraphs provides a basis for a claim under the False Claim Act. Every material "disclosure" had already been previously reported in the news media.

Second, Relator never fulfilled the second requirement of being an original source, "voluntarily provid[ing] the information [on which the allegations are based] to the state . . . before filing an action based on that information." Cal. Gv't Code § 12652(d)(3)(B) (emphasis added). This requirement, unique to original sources, is designed to "encourage greater cooperation between the potential *qui tam* plaintiffs and the State or prosecuting authority prosecuting the action." RJN Ex. 25. (Certified Legislative History of Cal. Gov't Code § 12650-12656 at 74) (*Comments of the Center for Law in the Public Interest, original authors of the California False Claims Act*). Relator alleges compliance with § 12652(c)(3), but never alleges that she complied with § 12652(d)(3)(B) by sharing her information with the State before filing suit. This jurisdictional defect is fatal to her claims. *See Grayson*, 142 Cal. App. 4th at 757 (rejecting relator's contention that he was an "original source" because "plaintiff has failed to allege he did anything to voluntarily provide the information on which his allegations are based to the Controller or any other state official before he filed his *qui*

[7] While the Complaint appears to allege 211 paragraphs prior to asserting its various causes of action, it actually contains two sets of paragraphs 194-208. In addition, the final paragraph, the prayer for relief, is inexplicably labeled as paragraph 442. This numbering, together with the Complaint's references to Florida law (*see* ¶¶ 40-41), suggests that the Complaint is nothing more than a cut and paste from some prior proceeding.

tam lawsuit").

Third, and most fundamentally, Relator was not the "catalyst" for the many press reports that previously disclosed the basis of her suit (nor does she claim to be) and she therefore brought nothing new to the attention of the State. That is undoubtedly why the State declined to intervene in it. Most prominent among those news media reports was the December 18, 2006 *New York Times* article, which itself reveals that the catalyst for that disclosure was "a lawyer representing mentally ill patients." RJN Ex. 12. Indeed, the United States District Court for the Eastern District of New York issued a lengthy opinion regarding those circumstances which had nothing to do with Relator. *See In re Zyprexa Injunction*, 474 F. Supp. 2d 385 (E.D.N.Y. 2007).

In sum, rather than satisfy each of the three elements of the test for meeting "original source" status, Relator fails them all. Relator bears the burden of proof on each of these elements, Cal. Gov't Code § 12654(c), the failure of any one of which is fatal to her claim. The Court has no jurisdiction over Relator's CFCA claims.

II. RELATOR LACKS STANDING TO ASSERT AN UNFAIR COMPETITION AND FALSE ADVERTISING CLAIMS

Standing to bring suit under the California Unfair Competition Law ("UCL") and the California False Advertising Law ("FAL") is limited to specified public prosecutors on behalf of the State of California and to injured private parties on their own behalf. California Business & Professions Code §§ 17204, 17535. Relator is neither a public prosecutor nor an injured party. She therefore lacks standing to assert either a UCL or false advertising claim, both of which should therefore be dismissed. *See Grayson*, 142 Cal. App. 4th at 757-758 (dismissed the unfair competition claims asserted by a *qui tam* plaintiff dismissed for lack of standing).

A. Relator Is Not A Public Prosecutor

Under the UCL, standing to bring suit on behalf of the people of the State of California is limited to specified public prosecutors, of whom Relator is not one. Civil actions under § 17200 may be brought in the name of the People of the State of California by (1) the Attorney General, (2) any district attorney, (3) city attorneys or (4) with the consent of the district attorney, by any city prosecutor in any city having a full-time city prosecutor. Cal. Bus. & Prof. C. § 17204.

See, e.g., California Consumer Health Care Council v. Kaiser Foundation Health Plan, Inc., 142 Cal. App. 4th 21, 33 (2006) ("[as amended] the UCL now authorizes the filing of injunctive and restitutionary relief only by certain public prosecutors and by 'any person who has suffered injury in fact'").

While the law allowed for "private attorneys general" suits under the UCL prior to 2004, such representative actions by "private attorneys general" was expressly revoked by the adoption of Proposition 64.[8] "After Proposition 64, which the voters approved at the November 2, 2004 General Election, a private person has standing to sue only if he or she 'has suffered injury in fact and has lost money or property as a result of such unfair competition.'" *California for Disability Rights v. Mervyn's, LLC*, 39 Cal. 4th 223, 227 (2006) (emphasis added) (quoting Cal. Bus. & Prof. C. §17204). Proposition 64 revoked standing for private attorneys general under the false advertising laws just as it did under the UCL. *See Anuziato v. eMachines, Inc.*, 402 F. Supp. 2d 1133, 1136-7 (C.D. Cal. 2005) (Proposition 64 "eliminated the so-called 'unaffected plaintiff' standing. Under both the UCL and the FAL, a plaintiff must now have suffered injury and lost money or property" to have standing to sue.)

B. Relator Is Not An Injured Private Party

Relator also lacks standing to bring suit for individual recovery under the UCL and FAL. Proposition 64 "eliminated the so-called 'unaffected plaintiff' standing. Under the UCL and the FAL, a plaintiff must now have suffered injury and lost money or property" to have standing to sue. *Anuziato*, 402 F. Supp. 2d at 1136-7. *See* Cal. Bus. & Proc. C. § 17204 (standing to bring a claim for relief under the UCL also exists for "any person who has suffered injury in fact and has lost money or property as a result of such unfair competition.")

The complaint is devoid of any such allegations that plaintiff suffered an injury.

[8] The Unfair Competition Law never authorized *qui tam* suits. "With antecedents older than the republic, the *qui tam* action is a type of private attorney general lawsuit; it allows an individual to sue to enforce a public statutory right and to retain a portion of any moneys recovered thereby." *In re Biddle*, 52 Cal. App. 4th 396, 398 (1997). "By definition, *qui tam* rights have never existed without statutory authorization. As a result, courts have been required to develop criteria to determine whether a given statute in fact authorizes *qui tam* enforcement. Traditionally, the requirements for enforcement by a citizen in a *qui tam* action have been (1) that the statute exacts a penalty; (2) that part of the penalty be paid to the informer; (3) that, in some way, the informer be authorized to bring suit to recover the penalty." *Sanders v. Pacific Gas & Electric Co.*, 53 Cal. App. 3d 661, 671 (1975). Section 17200 lacks these prerequisites.

Rather, Plaintiff's UCL and false advertising claims are premised exclusively on injuries allegedly suffered by the State of California and the general public. *See, e.g.*, Complaint ¶¶ 240, 242, 250, 251 (alleging Defendant is in "receipt of billions of dollars of ill-gotten gains from the sale and prescription of Zyprexa in California" for which Relator seeks "restitution" and "disgorge[ment]" on behalf of the State of California).

The lack of injury in fact is fatal to any individual standing to bring a UCL or FAL claim. *See, e.g.*, *Grayson*, 142 Cal. App. 4th at 757 (Plaintiff's UCL claims dismissed following Proposition 64 because he had not – and could not – allege any injury in fact): *Mortera v. North America Mort. Co.*, 172 F. Supp. 2d 1240, 1241 (N.D. Cal. 2001) (remanding a pre-Proposition 64 UCL claim because plaintiff had suffered no injury in fact and "does not herself claim to be a veteran or otherwise eligible for the VA program, nor does she allege to have been personally injured by North American's allegedly illegal loan practices").

III. THE COMPLAINT FAILS TO STATE A CLAIM FOR VIOLATION OF THE CFCA

To state a claim under the FCA or CFCA, a complaint must identify (1) a "claim" submitted by the defendant that (2) was false or fraudulent (3) with knowledge of the falsity or fraud. *United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1000 (9th Cir. 2002).[9] In addition, a complaint under the FCA or CFCA must meet the more stringent pleading requirements of Rule 9(b) that averments of fraud or mistake be pleaded with particularity. *State of Cal. ex rel. Mueller v. Walgreen Corp.*, 175 F.R.D. 631, 636 (N.D. Cal. 1997) (articulating reasons why Rule 9(b) applies to CFCA claims); *United States v. Sequel Contractors, Inc.*, 402 F. Supp. 2d 1142, 1152 (C.D. Cal. 2005) (applying Rule 9(b) to CFCA). Relator fails to meet every one of these requirements.

A. Relator Fails To Allege Her Claim With Particularity

Relator alleges that Lilly violated the CFCA without ever identifying a single claim

[9] Because the CFCA is patterned after the Federal False Claims Act, 31 U.S.C. § 3729 *et. seq.*, federal decisions interpreting the Federal False Claims Act are persuasive on the meaning of the CFCA. *State of Cal. ex rel. Bowen v. Bank of America Corp.*, 126 Cal. App. 4th 225, 236, 240 n.11 (2005); *Laraway v. Sutro & Co., Inc.*, 96 Cal. App. 4th 266, 275 (2002).

for payment or government reimbursement. Compl. ¶¶ 212-233. A false claims act lawsuit such as this one that fails to identify a "claim" is not cognizable, even if the complaint otherwise details allegedly unlawful conduct. *See e.g., Aflatooni*, 314 F.3d at 1002 (FCA "focuses on the submission of a claim, and does not concern itself with whether or to what extent there exists a menacing underlying scheme"); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996) (FCA "attaches liability, not to underlying fraudulent activity, but to the 'claim for payment'") (citation omitted); *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (dismissing a complaint that failed to show "*an actual false claim* for payment being made to the Government") (emphasis in original); *see also U.S. v. University of San Francisco*, 2006 WL 2884331, *6 (N.D. Cal. Oct. 10, 2006) (dismissing FCA claims where plaintiff failed to demonstrate independent knowledge of the alleged fraud and failed to allege with sufficient particularity); *United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1215-16 (E.D. Cal. 2002) (dismissing FCA claims in the complaint and amended complaint for failure to identify a claim); *United States ex rel. Rost v. Pfizer, Inc.*, 446 F. Supp. 2d 6, 27 (D.Mass. 2006) (dismissing FCA claim similar to the one here, though it alleged in "great detail" defendant's alleged illegal marketing of drug, where Complaint did not identify specific false claim).

Instead of alleging any particular false claim, Relator proffers conclusory allegations about what must have resulted from Lilly's alleged off-label promotion of Zyprexa and alleged payment of "kickbacks" to physicians. Compl. ¶¶ 202-211.[10] Such "must have" allegations fail to satisfy Rule 9(b), which requires particularity with respect to specific transactions. In the Ninth Circuit, "particularity" requires the precise "time, place, and nature of the misleading statements, misrepresentations, [or] specific acts of fraud." *Kaplan v. Rose*, 49 F.3d 1363, 1370 (9th Cir. 1994) (citations omitted); *Rost*, 446 F. Supp. 2d at 27-28. The Complaint fails to plead any of these facts. It does not include, for example (1) the amount of the claim, (2) when it was allegedly submitted for reimbursement, (3) the identity of the doctor or pharmacy submitting the claim, (4) the nature of the

[10] With regard to the "kickback" allegations, the Complaint does not detail any physician who received a "kickback" or any specific claims submitted as a result of the alleged "illegal kickback arrangement(s)." Compl. ¶ 205, p. 43. Nor does the Complaint identify any specific seminars or honoraria forming part of the alleged "kickback" scheme. Absent such facts, the Complaint does not satisfy Rule 9(b) with regard to the "kickback" claims.

claim submitted and why it was allegedly false, including the reasons why the specific claim violated either the FDCA or AKS. Absent such facts, the Complaint fails to satisfy Rule 9(b)'s requirements, and dismissal is required. *See County of Santa Clara v. Astra USA, Inc.*, 428 F. Supp. 2d 1029 (N.D. Cal. 2006) (applying FRCP 9(b) to California False Claims Act claim and dismissing claim that drug manufacturers submitted false claims for payment where plaintiff failed to allege with any specificity whether any improper claims were submitted and did not specify the drugs alleged to have been overpriced, the manufacturers who sold the drugs or the prices charged.

B. Relator Fails To State A Claim Because Her Theory of Material "Falsity" Is Legally Deficient

1. Relator Does Not Allege Conduct Meeting The CFCA's Definition of "Falsity"

Putting aside Relator's failure to plead with particularity any alleged "claim" at all, Relator's CFCA causes of action fails because it does not allege falsity. A "false" claim is a claim containing a untrue statement. *See Wang*, 975 F.2d at 1421 ("'known to be false' does not mean scientifically untrue, but rather a 'lie.'"); *U.S., ex rel. Haight v. Catholic Healthcare West*, 2007 WL 2330790, *2 (D. Ariz. Aug. 14, 2007). A Complaint resting merely on an allegation of an unreimbursable claim, without more, does not therefore state a claim under the FCA and must be dismissed. *See, e.g., U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127, *9 (E.D. Mo., April 21, 2006) (unpublished) (dismissing FCA claim similar to the one made here where plaintiff did not allege that defendant drug manufacturer "deliberately lied nor that the data provided by defendant either to its sales representatives or to doctors was incorrect or false").

Here, there is no allegation in the complaint that any claim for reimbursement contained any false statement, any misrepresentation, or any lie. Rather, the most that plaintiff argues is that (unidentified) claims for reimbursement were "false" because they sought reimbursement for off-label use of Zyprexa.[11] Compl. ¶¶ 37-51. In other words, Relator's CFCA

[11] Because the erroneous allegation to the contrary on which Lilly's claim rests is one of law, not fact, the Court need not, and should not, accept it as true in deciding whether the Complaint states a claim. *See Western Mining Council v. Watt*, 643 F. 2d 618, 624 (9th Cir) (courts need not accept legal conclusions "cast in the form of factual allegations.")

claim depends on her assertion that all claims seeking reimbursement for off-label use of Zyprexa are automatically "false" under the CFCA. But this is not so: "falsity" requires a showing that the claim at issue contained a untrue statement. In other words, there is nothing "false" about seeking reimbursement for even non-reimbursable claims so long as the claim does not contain any misrepresentation. Here, Relator does not allege that the claims contained any untrue statement about the diagnosis of the patients treated with Zyprexa or the nature of treatment provided and she does not therefore state a claim under the CFCA.

Moreover, Relator's presumption that off-label uses are not reimbursable is in fact legally incorrect. Physicians are free to prescribe drugs for off-label uses, and to request reimbursement from state and federal healthcare programs when they do so. "[N]either Congress nor the FDA has attempted to regulate the off-label use of drugs by doctors and consumers. A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA." *Washington Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000). In fact, off-label prescribing is not only permitted, but it has become commonplace in modern medical practice. *Id*. As the FDA has stated, "'unapproved' or more precisely 'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact reflect approaches to drug therapy that have been extensively reported in medical literature." *See In re Orthopedic Bone Screw Products Liability Litig.*, 159 F.3d 817, 830 (3rd Cir. 1998), *rev'd on other grounds*, *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Indeed, in many cases, off-label prescribing may be essential to giving patients optimal medical care, and therefore required by medical ethics. *Id.* at 350 n. 5.

Because physicians frequently *must* prescribe off-label to best ease their patients' suffering or even save their patients' lives, federal law does not condition Medicare reimbursement on whether the FDA has approved a particular use, but rather looks to other factors as well, including whether the use is listed in medical compendia (which list both on- and many off-label indications), and whether the particular hospital in which the drug was prescribed has approved the

drug for that use. *See* 42 U.S.C. § 1395x(t).[12] The Medicare Benefit Policy Manual—the authoritative publication governing Medicare coverage—implements that statutory mandate, explicitly instructing Medicare carriers to decide whether to reimburse for off-label uses of drugs on a case-by-case basis. RJN Ex. 5. (Ch. 15, Medicare Benefit Policy Manual at 50.4.2 – Unlabeled Use of Drug) ("FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. . . . *These decisions are made by the contractor on a case-by-case basis*.") (emphasis added).

Medicaid likewise authorizes the reimbursement of drugs prescribed for off-label uses. The Social Security Act authorizes Medicaid programs to cover all "prescribed drugs." 42 U.S.C. §§ 1396a(a)(10)(A) and 1396(a)(12); 42 C.F.R. §440.120(a). In addition, the Act directs States that accept federal funds to reimburse for any "medically accepted indication," which specifically includes off-label uses that are "included or approved for inclusion" in certain compendia. 42 U.S.C. §1396r-8(k)(6). As the Complaint itself recognizes, the State of California looks to compendia, including the Drugdex Information System, to determine whether it will reimburse a particular usage of a drug. (Compl. ¶ 39). Significantly, the DRUGDEX information system explicitly identifies Zyprexa as being "[e]ffective in low does" for dementia. RJN Ex. 6 at 71.[13]

2. Relator Does Not Allege Any "Material" False Statements.

In addition to falsity, to be actionable under the CFCA, a statement must also be material. *City of Pomona v. Superior Court*, 89 Cal. App. 4th 793, 802 (2001). Where a plaintiff alleges a false claim based on off-label promotion, the materiality requirement requires that a plaintiff allege with the required specificity that defendant's allegedly false statements were material to the reimbursement decision. Thus, in *Hess*, the court held that plaintiff could not meet the

[12] Federal authority regarding reimbursement is relevant because the Complaint alleges that the State of California's Medi-Cal program adheres to federal guidelines in determining what claims are eligible for reimbursement.

[13] The Court may take judicial notice of documents referenced in the Complaint. *Mersnick v. USProtect Corp*., 2007 WL 2669816, *2 (N.D. Cal. September 07, 2007).

materiality requirement, where he based his FCA claim on allegations that defendant had promoted a drug for the off-label use of treating a particular stage of cancer, but the Medicare claim form at issue did not require a doctor to indicate what stage cancer the patient had. 2006 WL 1064127, at *7. The court reasoned that if the claim form did not require this information, than any statements about use of the drug to treat a particular stage of cancer could not be material. *Id.*

The absence of any material falsity in this case is apparent from the actual claims forms in use by Medi-Cal for prescription drugs. Those forms, of which this Court may take judicial notice, contain a field for a provider/pharmacist to enter the diagnosis of the patient to whom the drugs were prescribed. RJN Ex. 24 (Pharmacy Claim Form 30-1 and instructions for completion). Significantly, the claim form requires no certification or assurance that the prescription is for an on-label use; physicians are free to make plain in this form that the prescription is for an off-label use, and the State is free to reimburse (or not) as it sees fit. There is no falsity in such a reimbursement claim. More importantly, the instructions for completion of this form explicitly state that the fields regarding patient diagnosis are "optional." The optional nature of this information demonstrates a fatal defect in Relator's claims: the diagnosis, and consequently the on-label or off-label nature of the prescription, was immaterial to the State, since it made the information optional.

3. Relator's Causation Theory Is Legally Deficient

The claim form also reveals another fatal defect in Relator's claim: in order to be held liable under the CFCA, a defendant must "knowingly cause" the submission of a false claim. Cal. Gov't Code §12651(a)(1). Under the CFCA, "knowingly" means "actual knowledge" that the information was untrue or "deliberate ignorance" or "reckless disregard" of the truth or falsity of that information. Cal. Gov't Code §12651(a)(2). Moreover, a defendant "causes" another party to submit a false claim only when the submitting party is "merely a conduit" for the defendant. *See U.S. ex rel. Drescher v. Highmark, Inc.*, 305 F. Supp. 2d 451, 460 (E.D. Pa. 2004); *United States ex rel. Kinney c. Hennepin County Medical Center*, 2001 WL 964011, *9-10 (D. Minn. Aug. 22, 2001).

Relator has failed to plead allegations meeting this "knowingly caused" requirement. The Complaint alleges only that Lilly, through its sales representatives, provided physicians with information regarding off-label use of Zyprexa. Physicians are "learned intermediaries," who stand

between Lilly, the manufacturer, and any reimbursement that they decide to pursue. *See, e.g.*, *Garside v. Osco Drug, Inc*, 976 F.2d 77, 80 (1st Cir. 1992). Physicians make their own decisions about whether to prescribe Zyprexa at all, whom to bill, and what to say on the claim form. Because they act on their own accord and exercise discretion in whether, and how, to describe the diagnosis of the patients to whom they prescribe Zyprexa, they cannot conceivably act as Lilly's "mere conduits." There is not – and could not be – any allegation that Lilly exercised any control over or otherwise caused physicians or pharmacies to fill out claim forms in any particular manner or had any basis to believe whether and how they would do so. Relator's allegations are therefore not sufficient to meet the CFCA's "knowingly caused" requirement.

CONCLUSION

For all of the reasons expressed above, defendant Eli Lilly and Company respectfully requests that the Court dismiss Relator's complaint with prejudice.

Dated: September 28, 2007

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